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Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Vol. III, No. 11/July 2003

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WASHINGTON G-2 REPORTS

Established 1979

Will Correlogic's "Breakthrough" Cancer Testing Technology Gain Market Acceptance?

A novel protein pattern blood testing technique developed by Correlogic Systems (Bethesda, MD) for the early detection of various cancers has shown tremendous promise in research studies. For example, in a study published early last year in the British medical journal *The Lancet*, the Correlogic method was shown to have an overall predictive value of 94% for detecting ovarian cancer versus 35% for the traditional test, CA-125.

"This is something we've been waiting for. A simple cancer blood test would revolutionize the treatment for cancer. [The Correlogic test] appears to be the biggest breakthrough in cancer diagnostics ever," John Kovach, M.D., director of the Long Island Cancer Center at Stony Brook University (Stony Brook, NY), told the audience at the Wachovia Securities Cancer Diagnostics Conference in New York City, April 10. Kovach is an internationally known expert in cancer treatment and research who has no financial relationship with Correlogic.

Of course, successful research studies do not guarantee acceptance in the marketplace by laboratories and physicians. The real test for Correlogic's new technology is set to begin within the next few months when homebrew versions of its ovarian cancer test hit the market. For more on Correlogic and the outlook for its protein pattern testing technology, see *Inside The Diagnostics Industry*, pp. 5-7.

Correlogic At A Glance

Technology: Proteome Quest, protein pattern recognition software for detecting cancer
Founded: May 2000
Founders: Peter Levine, chief executive; Ben Hitt, Ph.D., chief science/technology officer
Headquarters: Bethesda, MD
Initial Funding: $1M from three angel investors
***Laboratory Partners*:** Quest Diagnostics and LabCorp
*For ovarian cancer test only

Correlogic's Ovarian Cancer Test Nears Market Introduction

Peter Levine

Market introduction for Correlogic's novel ovarian cancer test, Proteome Pattern Blood Test, is set to begin within months, according to chief executive Peter Levine. In a nutshell, the Correlogic test uses a proprietary software program to analyze blood protein patterns generated by a mass spectrometer.

The company signed licensing agreements with Quest Diagnostics (Teterboro, NJ) and LabCorp (Burlington, NC) in November 2002 for the commercialization of the test. Quest and LabCorp each tell *DTTR* that they are in the process of putting testing procedures in place for homebrew versions of the test at their esoteric testing labs. Quest plans to run the test at its Nichols Institute (San Juan Capistrano, CA) and LabCorp will perform testing at its Center for Molecular Biology and Pathology (Research Triangle Park, NC). The licensing agreements also cover any potential FDA-approved versions of the test as well.

Richard Bender, M.D., medical director for hematology/oncology at Quest's Nichols Institute, tells *DTTR* that the Correlogic test will initially be used as a compliment to the CA-125 test (formally known as cancer antigen 125).

CA-125 is used to monitor therapy during treatment for ovarian cancer and to monitor patients after treatment. The test is also sometimes used to follow high-risk women who have a family history of ovarian cancer but who do not yet have the disease. Medicare currently reimburses labs a maximum of $29.07 for CA-125 under CPT Code 86304.

Levine says that Quest and LabCorp perform a combined total of more than 300,000 CA-125 tests per year. He says that pricing for Correlogic's test has not yet been finalized, but he anticipates that it will be priced in a range similar to that of genotyping tests, which generally sell for $200 to $400 each.

The high cost of the test is largely a function of the expensive equipment needed to perform it, says Levine. A complete system costs roughly $600,000 to $1 million and includes 1) an automated sample handler; 2) a protein separation and/or ionization system; 3) a mass spectrometer; and 4) protein pattern recognition software developed by Correlogic.

Levine notes that Quest and LabCorp are currently the only two companies licensed by Correlogic and the terms cover only its ovarian cancer test. He says that Correlogic will seek licensing deals for other tests it is developing with its protein pattern blood testing technology, including tests for prostate and breast cancer.

Typically, Correlogic's licensing deals with laboratories include a four- to five-year term of exclusivity for a specific test. The laboratory pays Correlogic an 8% royalty on test sales and the royalty drops to 3% after the exclusivity period ends, according to Levine.

Ben Hitt, Ph.D., chief science and technology officer at Correlogic, is the inventor of the core algorithms that power Proteome Quest, the software that is used to

create computational "models" of disease states. The "hidden patterns" concept and process for identifying blood protein patterns associated with specific diseases was invented by Hitt, Levine, and scientists at the FDA and the National Cancer Institute. Levine says that Correlogic will pay undisclosed royalties to the National Institutes of Health for its exclusive license to the hidden-patterns technology once commercial test sales begin.

Challenges To Market Adoption Of Correlogic's Ovarian Cancer Test

DTTR observes that the Correlogic method may encounter market resistance because it analyzes protein patterns rather than a specific biomarker as most lab tests do. In addition, the estimated 10-fold increase in the expected cost of the Correlogic ovarian cancer test versus CA-125 could be hard for third-party payers to accept.

Levine contends that potential objections from physicians, patients, third-party payers regarding both price and the novel use of protein patterns will be overcome over time, given the ability of the Correlogic's test to detect ovarian cancer at its early stage.

According to the American Cancer Society (ACS), the five-year survival rate for ovarian cancer is 95% if diagnosed and treated when the disease is localized. But the survival rate drops to 31% once it has reached an advanced stage and metastasized. An estimated 25,400 women in the U.S. will be diagnosed with ovarian cancer this year and 14,300 will die from the disease, according to estimates from ACS.

Levine notes that the CA-125 test usually only discovers ovarian cancer after it has reached an advanced stage and survival rates are low. In early stages, when treatment is most effective and the survival rate is high, the CA-125 test is able to detect abnormal antigen levels no more than 60% of the time.

In contrast, a paper published by *The Lancet* on Feb. 16, 2002, showed that in an analysis of 116 blinded blood samples—50 from patients with cancer and 66 with non-malignant disease—the Correlogic's method was able to correctly identify all 50 cases of ovarian cancer, including all 18 Stage I cases. The single flaw in the performance was predicting ovarian cancer in three of 66 control cases. Overall, the test had a predictive value of 94% (50 of 53) vs. 35% for CA-125.

Top Five Sites of Cancer Deaths For Women—2003 Estimates

	New Cases	Deaths
Lung	80,100	68,800
Breast	211,300	39,800
Colon	74,700	28,800
Pancreas	15,800	15,300
Ovary	25,400	14,300

Source: American Cancer Society

The *Lancet* study was conducted by researchers from the FDA/National Cancer Institute (NCI) Clinical Proteomics Program, Northwestern University Medical School, M.D. Anderson Cancer Center, and Correlogic.

What's more, on April 9, 2003, NCI announced that Correlogic, NCI, and FDA scientists had achieved further improved results. The team was able to detect ovarian cancer with 100% accuracy—again identifying all of the cases of ovarian cancer—but without any false positives.

Levine says that NCI-funded clinical trials for the test will begin soon. He hopes to submit a 510k application to the FDA within one year. Initially, Correlogic will seek to have the test approved for monitoring women for recurrence of ovarian cancer. This is the same designation of use for CA-125, although CA-125 is also used extensively by physicians "off-label" for testing women at high risk for ovarian cancer. Ultimately, Levine believes the Correlogic test could be used as a screening test for ovarian cancer.

In addition, Levine notes that Correlogic's protein pattern testing technology has shown promise in detecting prostate cancer. In a study published on Oct. 16, 2002 in the *Journal of the National Cancer Institute*, researchers found that the technology correctly identified 95% of prostate cancer cases (36 of 38) from a set of 266 blinded patient blood samples.

Most significantly, researchers were able to rule out prostate cancer for 71% of men with intermediate PSA scores (4-10), which would have allowed them to avoid an unnecessary biopsy procedure. Currently, most men with PSA scores between 4 and 10 are recommended for a biopsy, even though 75% to 80% of them do not have prostate cancer. The study was conducted by researchers from the FDA/NCI, the University of North Carolina Lineberger Comprehensive Cancer Center, and Correlogic.

Levine says that Quest and LabCorp each have an option to bring the protein pattern prostate cancer test to market in homebrew form as well as any FDA-approved versions of it. However, he notes that Correlogic's efforts have been focused on moving toward a clinical trial for the test and beginning the exploration of detecting aggressive versus indolent forms of the cancer.

Operating On A Shoestring Budget

Of course, innovative technology and promising clinical research do not guarantee market adoption. The IVD industry is littered with start-up companies with "breakthrough technologies" that never materialized into meaningful sales in the marketplace. Remember Careside, DNA Sciences, Avocet Medical, etc.? Each of these companies ran through tens of millions of dollars to bring their products to an uncertain market.

Meanwhile, *DTTR* estimates that Correlogic will bring its ovarian cancer test to market by year's end for less than $5 million. The company is majority owned by Levine and Hitt, and three other investors have provided $1.1 million to obtain a minority stake. Aside from some undisclosed milestone payments from Quest and LabCorp, Correlogic has received no other funding since its inception in May 2000.

"We run a tight ship. We've been able to make great strides on limited resources," notes Levine. The company employs only nine FTEs plus three contracted consultants at a small office/lab in Bethesda, MD. The key to operating on a shoestring budget has been Correlogic's ability to leverage off its relationships with FDA/NCI, university hospitals, and Quest and LabCorp. Such frugality should help Correlogic endure the likely long road to achieving market acceptance for its tests. ▲